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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Asgeir Saebo, *et al.*	Group No.:	1617
Serial No.:	09/544,084	Examiner:	Wang, S.
Filed:	04/06/2000		
Entitled:	**Conjugated Linoleic Acid Compositions**		

TRANSMITTAL OF APPELLANTS' REPLY BRIEF (PATENT APPLICATION - 37 CFR § 1.193)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: July 25, 2005 By: Susan M. McClintock
Susan M. McClintock

Sir or Madam:

Transmitted herewith, in triplicate, is the APPELLANTS' REPLY BRIEF in this application, with respect to the EXAMINER'S ANSWER mailed May 23, 2005, in response to the Appeal Brief filed February 28, 2005, and received in the Mail Room on March 2, 2005.

Applicants believe that no fees are necessary for filing this Reply Brief. However, if this is incorrect, the Commissioner is hereby authorized to charge payment of any fee(s) associated with this communication, and/or credit any overpayment, to **Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: July 25, 2005

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PATENT
Attorney Docket No. **CONLINCO-04286**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo *et al.*
Serial No.: 09/544,084 Group No.: 1617
Filed: 04/06/00 Examiner: Wang, S.
Entitled: **CONJUGATED LINOLEIC ACID COMPOSITIONS**

APPELLANTS' REPLY BRIEF

APPEAL NO.:

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Dated: July 25, 2005 By: Susan M. McClintock
Susan McClintock

Sir:

This Brief is in reply to the Examiner's Answer mailed May 23, 2005.

It is not believed that any fees are necessary for this reply. However, if any fees are necessary, the Examiner is hereby authorized to charge Deposit Account No. 08-1290 the fee associated with this Reply Brief and any other fees associated with this communication. Please reference Attorney Docket No.: CONLINCO-04286 when charging the Attorney Deposit Account. A request for oral examination is being filed concurrently herewith.

This Brief is transmitted in triplicate. [37 C.F.R. § 1.192(a)].

ARGUMENT

The Office's acceptance of the statements of the real party in interest, related appeals and interferences, status of claims, status of amendments after final, summary of invention, issues, grouping of the claims, and claims appealed is appreciated. Additionally, the Office's removal of the Obviousness Type Double Patenting Rejection is appreciated. Below, Appellants specifically address the following issues from the initial Appeal Brief:

Issue 1 – Whether Claims 1-18 and 31 are obvious over the Cook patent in view of WO97/18320 (hereinafter, "the Cain patent") and U.S. 3,162,658 (hereinafter, "the Baltes patent") in further view of U.S. 5,885,594 (hereinafter, "the Nilsen patent").

A. Issue 1 - Claims 1-18 And 31 Are Not Obvious Over The Combination Of The Cook, Baltes And Nilsen Patents.

Claims 1-18 and 31 remain rejected under 35 U.S.C. §103(a) as allegedly being obvious over the combination of the Cook, Baltes, and Nilsen patents. The Office has failed to establish a *prima facie* case of obviousness because 1) the Office has not provided a motivation to combine the references; 2) the Office is applying hindsight reconstruction; 3) the Office is improperly disregarding the Sæbo Declaration; and 4) the Office is misapplying the law.

1. There Is No Motivation To Combine The References In The Manner Indicated By The Office

The Office fails to provide suitable evidence of a motivation to combine the Cook, Baltes, and Nilsen patents, thus a *prima facie* case of obviousness has not been established. The Office has made the following statements:

> In this case, the teaching suggestion and motivation are found both in the cited references and the knowledge generally available to one of ordinary skill in the art. In instant situation, it is a fact that the employment of CLA

> as a food ingredient was known, it is a fact that using alcoholic catalyst for making CLA was also known. The employment of CLA made by alcoholic catalyst for food would have been obvious to one of ordinary skill in the art. ***There is no need of invoking the high level of skill in the art.*** It is true that Baltes et al. did not teach or suggest the employment of CLA obtained therein for food product. But that is simply because at the time Baltes's invention was made, CLA had not been known as useful in food product. Considering the cited references as a whole, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the invention was made, to employ alcoholate catalyst, such as potassium methylate, for isomerization of linoleic acid to obtain CLA, and incorporate the obtained CLA into food products. Examiner's Answer, page 6.

Applicants respectfully submit that these statements are **misapplications of the law**.

The Office's basic argument is that **if** two things are well known (alcoholate catalysis and CLA in food), **then** the combination of the two things is well known (using CLA produced by alcoholate catalysis in food). Indeed, the Office goes so far as to state that in such circumstances, "[t]here is no need of invoking high level of skill in the art." This reasoning is completely devoid of any motivation to combine. Indeed, the only reasoning provided is that the two things are "well known."

The Federal Circuit has expressly forbidden this approach:

> The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. **Instead, the Board merely invoked the high level of skill in the art.** If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness (Emphasis added).

In re Rouffet, 47 USPQ2d 1453 (Fed. Cir. 1998). In the instant application, the sole basis for combination is the allegedly "well-known" status of two separate concepts. The Examiner's combination on this basis is inadequate as a matter of law.

The Office has also failed to analyze the invention as a whole. When analyzed as a whole, the use of a method for making CLA is non-obvious when the CLA is going to be utilized for food. "That each element in a claimed invention is old or unpatentable does not determine the nonobviousness of the claimed invention as a whole." *Custom Accessories v. Jeffrey-Allan Industries Inc.,* 807 F.2d 955, 1 USPQ 2d 1196, 1198 (Fed. Cir. 1986); See also *Brantingson Fishing Equipment Co. v. Shimano American Corp.*, 9 USPQ 2d 1669, 1672 (Fed. Cir. 1988). Put another way: "Only God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 225 USPQ 26, 31 n. 3 (Fed. Cir. 1985) (quoting from Markey, "Why Not the Statute," 65 JPOS 331, 333-334 (1983)).

The Office further contended:

> As to Baltes' teaching, the examiner restates that Baltes reference does not expressly limited to produce CLA for coating. Note question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art a the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. Contrary to applicants' assertion, Baltes state "The invention relates to a process for substantially complete catalytic conversion of compounds of unconjugated polyethenoid acid into compounds of conjugated enthenoid acid." (column 1, lines 13-16). "It will be appreciated from the above that this invention is not limited to the materials, steps, conditions and other details specifically described above and can be carried out with various modification. Thus, it will be understood that the process of this invention is broadly applicable to any unconjugated polyehtenoid acid compounds and products containing them." (column 8, lines 20-50, examiner emphasis added). Baltes particularly claims the process for the catalytic isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers using alkali metal monohydric alcoholate (see, particularly, claim 10-12).

> Office Action dated August 25, 2004; Paper Number 20040819; pages 4-6-7.

The Office takes this statement completely out of context. As pointed out in the Declaration of Asgeir Sæbo (discussed in more detail below), Baltes teaches the use of alcoholate catalysts to produce CLA for use in industrial products such as paints and varnishes. **Baltes fails to address the use of CLA made by these methods in food products.** Indeed, the Examiner now admits that Baltes fails to address the use of CLA made by these methods for food products: "***It is true that Baltes et al. did not teach or suggest the employment of CLA obtained therein for food product.*** **But that is simply because at the time Baltes's invention was made, CLA had not been known as useful in food product.**" Examiner's Answer; page 6 (emphasis added). Thus, a person of ordinary skill in the art reading Baltes would interpret the statement quoted by the Office as teaching that the processes of Baltes could be used to produce CLA for use in industrial type products, not food products. As such, this so-called "suggestion" from Baltes cannot serve as motivation to combine the references.

2. The Office's Reasoning Demonstrates Hindsight Reconstruction

The Office has applied hindsight reconstruction to combine the Cook, Baltes, and Nilsen patents. As noted in the *In re Rouffet* case cited above, hindsight reconstruction is not permitted. The Office, however, continues to rely upon *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) for the proposition that:

> [I]t must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Examiner's Answer; page 7.

To the extent that this 1971 C.C.P.A. case appears to condone hindsight reconstruction when providing a motivation to combine references, the Federal Circuit has *sub silentio* overruled this proposition, and has emphatically stated that hindsight reconstruction is not proper (as detailed below).

The Examiner further states:

> As to Baltes' teaching, the examiner restates that Baltes reference does not expressly limited to produce CLA for coating...Contrary to applicants' assertion, Baltes state 'The invention relates to a process for substantially complete catalytic conversion of compounds of unconjugated polyethenoid acid into compounds of ethenoid acid.' (column 1, lines 13-16). 'It will be appreciated from the above that this invention is not limited to the materials, steps, conditions and other details specifically described above and can be carried out with various modifications. Thus, it will be understood that the process of this invention is broadly applicable to **any unconjugated polyethenoid acid compounds and products containing them.**' (column 8, lines 20-50, emphasis added)... ***It is true that Baltes et al. did not teach or suggest the employment of CLA obtained therein for food product.*** **But that is simply because at the time Baltes's invention was made, CLA had not been known as useful in food product."** Examiner's Answer; pages 7-8.

The Examiner continues to misapply the law regarding hindsight analysis. Indeed, **the Examiner admits that the Baltes reference does not teach or suggest the employment of CLA for food product.** As such, the only way the Examiner could glean that Baltes teaches and suggests the employment of CLA for food product is through hindsight analysis. The Federal Circuit has repeatedly warned against using hindsight reconstruction as a test of obviousness. A few examples of such cases include: *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) ("One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention"); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720 (Fed.

Cir. 1990) (The inappropriateness of hindsight as a test of obviousness was, in point of fact, discovered, and articulated lucidly, over three centuries ago, by Milton, who, in Paradise Lost Part IV, L. 478-501, stated "The invention all admired, and each how he To be the inventor missed; so easy it seemed, Once found, which yet unfound would have thought, Impossible!"); *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068 (Fed. Cir. 1993) ("The motivation to combine references can not come from the invention itself"); *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction-an illogical and inappropriate process by which to determine patentability"); *W.L. Gore & Assocs., Inc. v. Garlock Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with the knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher ..."). Accordingly, to the extent the Office has admitted reliance on hindsight reconstruction, that reliance is misplaced as a matter of law.

3. The Office Has Ignored Evidence Presented By The Applicants That Establishes That Patentable Weight Should Be Given To The Combination Of Adding Alcoholate Catalyzed CLA To Food Products.

Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products in non-obvious. The Office, however, continues to ignore the evidence presented by the Applicants establishing that patentable weight should be given to the combination of adding alcoholate catalyzed CLA to food products. In particular, in reference to the patentability of the claims, the Office stated:

> [R]egarding the limitation about the method to obtain the conjugated linoleic acid, note a method of making ingredients is not seen to render patentable weight to a method which employs such ingredients, absent evidence to the contrary." Office Action dated July 16, 2003; Paper Number 20030716; page 4.

Applicants first note that this statement ignores the actual language of the claims, which specify the particular step of using an alcoholate catalyst. This is contrary to the Office's statement that the claims only employ such ingredients. **Applicants fail to see how the Office can simply ignore a process step and reason that a specific step cannot provide patentable weight to a method claim.** The Office provided no legal authority on this point. Applicants are not aware of any such legal precedent.

Furthermore, Applicants **have provided** evidence that it is not obvious to use a process that was previously used for the production of CLA for industrial uses with a method for food production. This evidence is provided by the Declaration of Asgeir Sæbo (provided at Appendix B). As detailed in the Sæbo Declaration, none of the references teach or suggest using CLA isomerized with alcoholate catalysts in food products. Furthermore, as explained by Dr. Sæbo, the Baltes patent discloses the use of oils with high levels of triunsaturated fatty acids. These oils are not generally suitable for the production CLA for oral consumption.[1] Thus, the Office's attempt to claim that the compositions of Baltes could be used in a food product is misguided and contradicted by the Examiner's own reasoning.

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[1] Indeed, the Examiner readily admits, "***It is true that Baltes et al. did not teach or suggest the employment of CLA obtained therein for food product.*** **But that is simply because at the time Baltes's invention was made, CLA had not been known as useful in food product.**" Examiner's Answer; pages 6 and 8 (emphasis added).

The Applicants **have provided evidence** as to why a method that uses CLA produced by alcoholate catalysis to make food products is non-obvious. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

> **Office personnel should consider all rebuttal arguments and evidence presented by applicants**. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id. See also In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).
> * * *
> A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.[2]

Additionally, the Courts have held as follows:

> When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.[3]

Furthermore:

> If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by

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[2] MPEP §§2144.08; emphasis added).

[3] *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

> experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.[4]

Accordingly, even if the Office had established a *prima facie* of obviousness in a preceding office action (and Applicants contend that he did not), the Examiner must respond to Applicants arguments. The failure to rebut either the arguments or the evidence advanced by the Applicants is reversible error under *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996).

In re Alton is directly applicable to the present facts. Instead of addressing the arguments presented in the Sæbo Declaration, the Office has provided only conclusory statements and failed to address the particular evidence offered in the Declaration. In particular, the Sæbo Declaration provides evidence that:

- "The Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and conjugated linolenic acid (CLnA) for technical purposes such as drying oils and paint varnishes.
- The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conjugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in may ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in conventional manners."
- Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.
- Other disclosure in the Baltes patent also indicates the insuitabity of the methods for the production of edible CLA.
- The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunstaurated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts

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[4] *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

of breakdown products and unwanted polymers, especially when conjugated.

- However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

The Examiner's attempted rebuttal, in its entirety, is as follows:

> The teaching of Baltes et al is not limited to the particular oil disclosed in the examples therein. Baltes teaches a general method for isomerising unconjugated polyethenoid to conjugated polyethenoid. See, column 1, lines 13-16. The starting material may be any unconjugated polyethenoide compounds or products containing them. See column 8, lines 20-68. Further, applicant appears to argue the employment of the reaction mixture to foodstuff, what is actually in the claims are the compounds, i.e., conjugated linoleic esters. ('to provide conjugated linoleic acid esters', see claims in instant application. The declaration merely provides applicant's interpretation of Baltes' teaching and no objective evidence for rebutting the prima facie case of obviousness." Examiner's Answer; pages 8-9.

The response is flawed because it completely fails to respond to any of the points listed above regarding the Sæbo Declaration. The Office states that Baltes is not limited to any particular oil. However, this fails to respond to the conclusion advanced by Mr. Sæbo that one skilled in the art would read the application to be directed to oils with high levels of triunsaturated fatty acids because a substitute for Tung oil was being sought. The Office further states that Baltes teaches the use of the resulting polyethenoid compounds for "any" product. However, this statement ignores the evidence advanced that a person of ordinary skill in the art would read Baltes as being directed to use of CLA for technical purposes, such as in paints in varnishes. The Office states that "applicant appears to argue the employment of the reaction mixture to foodstuff" and dismisses the argument the claims are allegedly (and mistakenly) to compounds. This is precisely the point and indeed, what is claimed! The Office asserts that the Sæbo Declaration provides no objective evidence and is based merely on opinion. Such a

baseless conclusion indicates that the Office has not properly considered the Sæbo Declaration. The Sæbo Declaration is based upon an objective and scientific analysis. Finally, the Office apparently forgets the fact that it now admits that, "***It is true that Baltes et al. did not teach or suggest the employment of CLA obtained therein for food product.***" Examiner's Answer; pages 6 and 8 (emphasis added). **The use of the method of Baltes to produce CLA for use in foodstuffs is not obvious. As discussed above, the Examiner has failed to examine the invention as a whole.**

As a result, Applicants respectfully request that the Examiner reconsider the evidence offered in the Sæbo Declaration. This evidence establishes that cited references cannot be properly combined and thus rebuts a prima facie case of obviousness. Accordingly, Applicants respectfully request that the claims be passed to allowance.

4. The Examiner's Citation Of *In re Boesch* Is Inappropriate

The Examiner has cited *In re Boesch*, 205 USPD 215 (CCPA 1980) for the proposition that:

> Further, purifying CLA composition by using silica gel (adsorbent) is seen to be obvious since silica gel is well known for purification and separation purpose. Having a limitation of the volatile organic compound (VOC) in food product (whether it the limitation after storage or before storage) is considered an optimization of a result effective parameter, which is considered within the skill of the artisan. Examiner's Answer; page 5.
>
> Appellants' arguments that amounts volatile organic compounds (VOC) is not a result effective variable for food product have been fully considered, but are not persuasive. If VOC would affect the quality of food products, every effort would have been made to control the amount of VOC in food products. e.g., Cook teaches that any solvent in CLA should be removed under vacuum, before the CLA could be used in a food product. See, particularly, column 2, lines 40-47. Examiner's Answer; page 9.

The Examiner is again respectfully directed to the MPEP at §2144.05 which states a "particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimization of workable ranges of said variable might be characterized as routine experimentation." The MPEP additionally cites *In re Antonie*, 559 F.2d 618 (CCPA 1997) for the proposition that the failure of the prior art to recognize a result-effective variable results in the nonobviousness of a claimed range. This is contrasted with *In re Boesch*, in which the court held that the prior art suggested proportional balancing to achieve desired results in the formation of an alloy.

In the instant case, the amount of VOC is not a result effective variable, it is a property which results from the proper treatment and handling of the CLA. It is noted, however, the underlying methods of treatment may involve result effective parameters, for example, silica adsorption with particular amounts of silica for the removal of metal ion contaminants. The claims are not limited to the methods and thus the result-effective variable analysis is inappropriate. Applicants further note that this treatment step is not recognized by the prior art as a treatment method for CLA products and thus, if it were claimed, **would actually establish the patentability of the claims.**

D. Conclusion

For the foregoing reasons, it is submitted that the Office's rejection of Claims 1-18 and 31 was erroneous, and reversal of the rejection is respectfully requested. Appellant requests either that the Board render a decision as to the allowability of the claims, or alternatively, that the application be remanded for reconsideration by the Office.

Dated: July 25, 2005

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APPENDIX A

CLEAN VERSION OF THE ENTIRE SET OF PENDING CLAIMS

1. (previously amended) A method for producing a food product containing conjugated linoleic acid esters comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters; and

c) combining said foodstuff with said conjugated linoleic acid esters from step (b) to produce a food product.

2. (original) The method of Claim 1, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

3. (previously amended) The method of Claim 1, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

4. (previously amended) The method of Claim 1, wherein step (c) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid esters and said foodstuff in step (d) to produce said food product.

5. (previously amended) The method of Claim 4, wherein said antioxidant is selected from the group consisting of α-tocopherol, β-tocopherol, lecithin, ascorbylpalmitate, and BHT.

6. (previously amended) The food product produced according to the method of Claim 1, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

7. (previously amended) A method for producing a food product containing conjugated linoleic acid comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters to provide conjugated linoleic acid; and

d) combining said foodstuff with said conjugated linoleic acid from step (c) to produce a food product.

8. (original) The method of Claim 7, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

9. (previously amended) The method of Claim 7, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

10. (previously amended) The method of Claim 7, wherein step (d) further comprises treating said conjugated linoleic acid esters with an adsorbing agent, providing an antioxidant and combining said antioxidant with said conjugated linoleic acid and said foodstuff in step (b) to produce said food product.

11. (previously amended) The method of Claim 10, wherein said antioxidant is selected from the group consisting of α-tocopherol, β-tocopherol, lecithin, ascorbylpalmitate, and BHT.

12. (previously amended) The food product produced according to the method of Claim 7, further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

13. (previously amended) A method for producing a food product containing conjugated linoleic acid triglycerides comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst, and

iii) a foodstuff; and

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) incorporating said linoleic acid esters into triglycerides to provide triglycerides containing conjugated linoleic acid moieties; and

d) combining said foodstuff with said triglycerides containing conjugated linoleic acid moieties from step (c) to produce a food product.

14. (original) The method of Claim 13, wherein said linoleic acid esters are derived from oils selected from the group consisting of safflower, sunflower, and corn oil.

15. (previously amended) The method of Claim 13, wherein said alcoholate catalyst is selected from the group consisting of sodium methylate, potassium methylate, sodium ethylate, and potassium ethylate.

16. (previously amended) The method of Claim 13, wherein step (d) further comprises treating said triglycerides containing conjugated linoleic acid moieties with an adsorbing agent, providing an antioxidant and combining said antioxidant with said triglycerides and said foodstuff in step (b) to produce said food product.

17. (previously amended) The method of Claim 16, wherein said antioxidant is selected from the group consisting of α-tocopherol, β-tocopherol, lecithin, ascorbylpalmitate, and BHT.

18. (previously amended) The food product produced according to the method of Claim 13 , further comprising an antioxidant selected from the group consisting of lecithin, ascorbylpalmitate, and BHT.

19-30. (canceled)

31. (previously presented) A method for producing a food product containing conjugated linoleic acid esters comprising:

a) providing:

i) linoleic acid esters,

ii) an alcoholate catalyst,

iii) a foodstuff;

b) treating said linoleic acid esters with said alcoholate catalyst to provide conjugated linoleic acid esters;

c) treating said conjugated linoleic acid esters under conditions such that the volatile organic compound content of said conjugated linoleic acid esters is less than 5 ppm after storage;

d) combining said foodstuff with said conjugated linoleic acid esters from step (c) to produce a food product.

APPENDIX B

Declaration of Asgeir Saebo

PATENT
Attorney Docket No. **CONLINCO-04286**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Asgeir Sæbo *et al.*
Serial No.: 09/544,084 Group No.: 1617
Filed: 04/06/00 Examiner: Wang
Entitled: **CONJUGATED LINOLEIC ACID COMPOSITIONS**

Declaration of Asgeir Sæbo

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: 10/15/01 By: Mary Ellen Wank

I, Dr. Asgeir Sæbo, state as follows:

1. My present position is Director of Research, Natural AS.

2. I have reviewed the above captioned patent application, of which I am an inventor, the Office Action mailed July 23, 2001, and the Cook, Baltes, and Lievense patents cited as prior art.

3. After review of the cited references, I conclude that the references do not teach methods of producing conjugated linoleic acid suitable for oral consumption with alcoholate catalysts. In fact, only one of the cited references, Baltes, teaches the use of alcoholate catalysts for any purpose. It is my understanding that in the Office Action the Examiner states that "[t]he citation of Baltes et al. (U.S. Patent 3,162,658) is to show the level of ordinary skill in the art."

4. Contrary to the Examiner's opinion, the Baltes patent is not applicable to the present invention because the Baltes patent teaches methods of making CLA and conjugated linolenic

acid (CLnA) for technical purposes such as drying oils and paint varnishes. In particular, Column 1, line 30 of the Baltes patent provides that "[t]he latter ones, namely the unconjugated polyethenoid acids occur in nature in large quantities, while conjugated polyethenoid acids are relatively seldom found in fats and oils of natural origin except for woods oils such as tung oil. The latter compound and also its derivatives are of great technical interest and therefore, many attempts were made to isomerize unconjugated polyethenoid acids to conjugated acids." The Baltes patent is solving the problem of providing substitute conjugated acids for naturally occuring conjugated acid sources such as tung oil. Therefore, the methods of the Baltes patent are intended to produce an oil suitable for the same purposes as tung oil. Tung oil is not edible and the tung tree is listed in the "Poisonous Plant Bibliography" of the United States Food and Drug Administration, Center for Food Safety & Applied Nutrition, Office of Plant and Dairy Food and Beverages. The intended use of the conjugated linoleic acids for technical purposes as opposed to nutritional purposes is further reaffirmed at Column 9, lines 47-60 of Baltes patent where it is stated that "[t]he compounds of conugated fatty acids obtained by the method of this invention, or mixtures containing these compounds, are valuable industrial products which can be used in may ways. . . . The polymers thus formed can be used as ingredients of lacquers or coating compositions in convential manners." Based on the disclosure of the Baltes, Cook and Lievense patents, one cannot conclude that the CLA resulting from the alcoholate catalysis process is suitable for use in products meant for oral consumption.

5. Other disclosure in the Baltes patent also indicates the insuitabity of the methods for the production of edible CLA. Conjugated acids are inherently unstable. Stability is related to the number of double bonds. The Baltes patent describes the conjugation of soybean oil (Examples 1, 2, 6, 8, 9, 10, and 11), cottonseed oil (Example 3), linseed oil (Examples 4 and 5), and fish oil (Example 7), all of which contain high levels of triunstaurated fatty acids. These oils are generally unsuitable for obtaining CLA for nutritional uses because the refinement results in products with substantial amounts of breakdown products and unwanted polymers, especially when conjugated. However, it is noted that the use of oils with high levels of triunsaturated fatty acids as starting materials for CLA and CLnA for technical purposes is preferred due to the superior drying properties of conjugated trienes.

PATENT
Attorney Docket No. **CONLINCO-04286**

6. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dr. Asgeir Sæbo

Date: Oct 12 2001